DEPARTMENT OF HEALTH & HUMAN SERVICES d1502b Public Health Service
RB 31

Certified/Return Receipt Requested

March 25, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Patrick A. Rolfes, Vice President
Chem-Tech Ltd.
4515 Fleur Drive #303
Des Moines, IA 50321

Ref.# - 98-KAN-012

Dear Mr. Rolfes:

During an inspection of your drug manufacturing facility located at 1006 Hobson Street, Pleasantville, Iowa, conducted on March 4 to 6, 1998, it was determined you manufacture a drug for human use (Liceall medicated shampoo), and a drug for veterinary use (Piperazine wormer). Our investigator found significant deviations from the Good Manufacturing Practice for Finished Pharmaceutical regulations (Title 21, Code of Federal Regulations, Part 211). Such deviations cause the drug products manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Our inspection found, among others, failure to routinely assay drug products as part of finished product release; failure to validate the calculation of nitrogen found in Piperazine 34%; failure to validate the reliance of supplier's certificates of analysis; failure to conduct an adequate drug stability program; failure to periodically test the water source for chemical and microbial quality; and, failure to maintain complete batch records.

The above is not intended to be an all-inclusive list of violations at your facility. As a manufacturer of human and veterinary drugs, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

We acknowledge that Mr. Kevin McCay, Plant Manager, has submitted to this office a response concerning our investigator's observations noted on the Form FDA 483. We have reviewed this response and have concluded that it is inadequate as follows:

1. Observation 4 - It is not clear from your response if you plan to test both products at intervals during the term of the stability program.

2. Observation 5 - This response is vague. Do you intend to initiate a water sampling plan for chemical and microbial analysis.

3. Observation 6 - Do you have data or background literature to support your statement regarding the survivability of microorganisms in your Liceall product.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps that are being taken, in addition to those in Mr. McCay's letter dated March 16, to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Larry H. D. Salmon (for)
W. Michael Rogers
District Director
Kansas City District